REMARKS/ARGUMENTS

Claims 1-7, 16-47, 49-52, 54-59, 63, 64, and 69-72 have been cancelled without prejudice pursuant to Examiner's requisition to cancel non-elected claims. Claim 68 has been previously cancelled. Claims 9, 48, 61, 62 and 73 are amended. New claims 75-93 have been added. Claims 8-15, 48, 53, 60-62, 65-67, and 73-93 are pending in this application.

Applicant wishes to thank Examiner Kam for the telephonic interview on November 9th, 2004 relating to discussion of several of the issues remaining with this application.

New claims 75-81 have been added to further define the present invention with respect to % sequence identity. Claims 75 and 76 depend from claim 61, claims 77 and 78 depend from claim 62, and claims 79-81 depend from claim 73. Support for claims 75-78 may be found, at least, at paragraph [0055], page 22 of the specification. Support for claims 79-81 may be found, at least, at paragraph [0073], page 28 of the specification.

New claims 82-93 have also been added to further define the present invention. Independent claim 82 relates to polynucleotides that hybridize to SEQ ID NO:4 or 11 wherein the complement of the polynucleotide encodes a polypeptide that induces mammalian oocyte activation. Support for claim 82 may be found throughout the application, for example paragraph [0053] page 21. New claims 83-93 further define the polynucleotides of claims 82 and 73. Support for these claims may be found for example in the claims as originally filed.

Claims 9 and 48 have been amended to cancel the phrase "or a conservative variant thereof".

Claims 61, 62 and 73 have been amended to replace the phrase "inducing oocyte activation" with the phrase "inducing mammalian oocyte activation". Support for this amendment can be found throughout the specification, and at least with reference to Figures 5-7 (and associated figure legends); paragraph [0179] page 68; paragraph [0182] page 69; and paragraph [0193] page 74.

Claims 61 and 62 have also been amended to include further structural definition of the encoded polypeptide. Support for this amendment may be found for example at paragraph [0007] page 4, paragraph [0008] page 5, paragraphs [0023-0024] page 11.

Claim 73 has also been amended to recite a sequence that hybridizes to the complement of the sequence as defined in SEQ ID NO: 4, or the complement of the sequence

as defined in SEQ ID NO:11. Support for this amendment may be found for example at least at paragraph [0014] page 8, and paragraph [0175] page 66 of the specification.

Amendment and cancellation of the claims at any time during the prosecution of this application are not to be construed as acquiescence to any of the objections/rejections set forth in the instant Office Action or any previous Office Action, and are done solely to expedite prosecution of the application. Applicants submit that claims were not added, cancelled or amended during the prosecution of the instant application for reasons related to patentability. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

Rejection under 35 U.S.C. 112, first paragraph

In Item 4 of the Action claims 8, 9, 11-15, 48, 53, 60-62, 65-67 and 73 have been rejected under 35 USC 112, first paragraph.

At page 9, 1st paragraph of the Action, Examiner contends that claim 73 is not enabled with respect to a nucleotide sequence that hybridizes to SEQ ID NO:4 or 11 and encodes a polypeptide that induces oocyte activation. However, in this same paragraph Examiner concedes that Figures 7A, 7B, and 7C show sequences that hybridize to the complement of SEQ ID NO:4 or 11.

Applicant submits that one of skill in the art would readily know that the sense strand, the antisense strand, or both strands of a sequence may be used within hybridization protocols. Furthermore, if one, or the other of the sense or antisense stands is shown to hybridize with one of the two strands of double stranded nucleic acid, the complementary strand would also hybridize with the other strand of the double stranded nucleic acid. As Examiner acknowledges, Figures 7A-C show hybridization of SEQ ID NO:4 or 11 to DNA obtained from a variety of sources, clearly demonstrating the property of hybridization under the stated conditions.

To further clarify claim 73, Applicant has amended this claim to include the phrase "hybridizes to the complement of the sequence" for each of the identified sequences in the claim, and new claim 82 has been added to define polynucleotides that hybridize to the sequences defined by SEQ ID NO:4 or 11. As one of skill in art would readily realize, both strands may be used to encode a polypeptide either directly or indirectly using standard protocols. For example, a sequence that hybridizes to SEQ ID NO:4 is used as the template to produce an RNA transcript encoding the polynucleotide. By convention, the strand that is listed in the sequence listing is the same as the RNA sequence, except that Us are indicated in

the RNA sequence that correspond to Ts in the DNA sequence. Once the sequence of a nucleic acid is known, an mRNA from the sequence may be readily obtained and the mRNA reversed transcribed to produce cDNA using standard techniques. Each of these templates may be used either directly, or indirectly to produce a polypeptide.

Claim 73 has also been amended to indicate that the function of the polypeptide encoded by the nucleic acid defined in the claim is limited to inducing mammalian oocyte activation.

Based on the amendments to claim 73 and associated arguments, Applicant requests withdrawal of the rejection to claim 73, and claims 8, 9, 11-15, 48, 53, 60, 65-67 that depend from claim 73, under 35 USC 112, first paragraph, as indicated in Item 3 of the Advisory Action.

Examiner contends, at page 9, 2nd paragraph of the Action that claims 61 and 62 are not enabled on the basis that "the specification does not provide sufficient written description for a genus of polynucleotide variants". Examiner has thus joined the enablement and written description provisions of 35 USC 112, indicating that satisfying the written description requirement (as presented in Item 5 of the Action) would also overcome the rejection based on enablement. Applicants respectfully traverse Examiner's rejection and submit that claims 61 and 62 comply with both the enablement and written description requirements.

As currently amended, claims 61 and 62 define a genus of polynucleotide variants that are 75% identical with either of SEQ ID NO: 4 or 11 and encode a polypeptide that induces mammalian oocyte activation. The feature of 75% identity provides inherent structural definition for the members of the claimed polynucleotide genus, while the feature of an encoded polypeptide inducing mammalian oocyte activation provides functional definition.

According to the USPTO Guidelines, (66 Fed. Reg. at 1106) the written description requirement can be met by "functional characteristics when coupled with a known or disclosed correlation between function and structure". In this regard, claims 61 and 62 are defined by both structure and function, with the correlation between structure and function being clearly disclosed in the specification.

Furthermore, the structural definition of the genus provided by "75% identical" is narrower than the teachings of the specification that demonstrates that the bovine and human PT32 sequences are 64.5% identical (see page 65, paragraph [171] of the specification) yet function in a similar manner.

The correlation of mammalian PT32 with the claimed functional feature of inducing mammalian oocyte activation is clearly described in the specification. As indicated at page 2,

paragraph 4 "recent studies seem to support the oscillogen hypothesis in mammals", while page 4, paragraph 6 states that "the sperm perinuclear theca protein is one such oscillogen". In this context, Applicants have provided extensive characterization of PT32 across various mammalian species. For example:

- microinjection of recombinant PT32 (rPT32) into bovine oocytes (see paragraph [0182] page 69) or Rhesus monkey oocytes (see paragraph [0193], page 74) resulted in oocyte activation;

- antibodies produced from PT32 selectively recognize sperm from Rhesus monkey (Figure 6), bull (Figure 5), and human (see paragraph [0179], page 68) again indicating biological recognition of PT32 across species boundaries.

Applicant submits that claims 61 and 62 are structurally defined in that "75% identical", in combination with the search parameters, provides structural definition to ensure that the members of the claimed polynucleotide genus are structurally similar to SEQ ID NO: 4 or 11. Furthermore, these sequences are functionally limited by the feature of inducing mammalian oocyte activation, and as indicated above, the correlation of the structure and function is clearly disclosed in the specification. Therefore, Applicant respectfully submits that claims 61 and 62 meet the written description requirement as outlined in USPTO Guidelines, (66 Fed. Reg. at 1106).

However, in order to expedite prosecution of the present application, claims 61 and 62 have been amended to further define the encoded polypeptide in a structural manner. The polypeptide is defined to comprise at least one of the sequence PPPGY (SEQ ID NO:1) and LPPAY (SEQ ID NO:2), and at least three domains comprising YGXPPXG (SEQ ID NO:3). Reconsideration of this rejection is therefore requested.

Still with regard to Item 5 of the Action, the Examiner contends that claim 73, and claims dependent therefrom (claims 8, 9, 11-15, 48, 53, 60 and 65-67), fail to meet the written description requirement in view of the polynucleotide genus defined according to hybridization conditions. Applicant respectfully traverses Examiner's rejection, again pointing to the USPTO Guidelines, 66 Fed. Reg. at 1106, that state that the written description requirement can be met by "functional characteristics when coupled with a known or disclosed correlation between function and structure". In claim 73 the recited hybridization conditions limit the members of the polynucleotide genus as being structurally similar to either SEQ ID NO: 4 or 11, while the recitation of "inducing mammalian oocyte activation" further defines the polynucleotide genus according to function.

In accordance with the above quoted passage from the Guidelines, the function limitation is proper as the correlation of structure and function is clearly disclosed in the specification. For example, PT32 is shown in Figures 7A, 7B and 7C to selectively hybridize with nucleic acids obtained from bovine, human, and rat testis, identifying similar sequences across species boundaries. Additional supportive data indicates that antibodies produced from PT32 selectively recognize sperm from Rhesus monkey (Figure 6), bull (Figure 5), and human (see paragraph [0179], page 68) and microinjection of recombinant PT32 (rPT32) into bovine oocytes (see paragraph [0182] page 69) or Rhesus monkey oocytes (see paragraph [0193], page 74) resulted in oocyte activation. Therefore, claim 73 satisfies the written description requirement, since claim scope is defined by both structure and function.

Moreover, Enzo Biochem v. Gen-Probe et al. (CAFC 01-1230; July 15, 2002; Panel opinion) in discussing the USPTO Guidelines approves the following example:

> "The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." (underline added)

As such, *Enzo* makes it clear that a polynucleotide genus can be adequately defined using hybridization conditions. Accordingly, Examiner's rejection is at odds with both the USPTO Guidelines as well as the CAFC opinion in *Enzo*.

Having regard to the above comments, Applicant requests withdrawal of the rejection to claims 8-15, 48, 53, 60-62, 65-67, and 73 under 35 USC 112, first paragraph, as was indicated in Item 3 of the Advisory Action.

In Item 5 of the Advisory Action, Examiner indicates that the only issue preventing allowance of the claims contained in the response dated November 17, 2004 is an issue under 35 USC 112, first paragraph with regards to claims 82-92. Examiner argues that the polynucleotide of claim 82 does not encode a polypeptide that induces mammalian oocyte activation. For the purpose of clarity, and to expedite prosecution of this application, claim 82 has been amended to further define the polynucleotide as having a complement that encodes a polypeptide that induces mammalian oocyte activation. Applicant submits that a sequence that hybridizes to SEQ ID NO:4 or 11 may, at least, serve as a template for mRNA synthesis, and be used by one of skill in the art, using common techniques, to produce a recited polypeptide.

Claims 83-92 incorporate this limitation by virtue of dependency. Accordingly, allowance of claims 82-92 is respectfully requested.

In the Advisory Action the Examiner states that "the nucleotide sequence that hybridizes to the sequence of SEQ ID NO:4 or 11 may be used indirectly to identify a nucleotide sequence that encodes a polypeptide having the activity of inducing oocyte activation". Applicant submits Examiner has narrowly interpreted the meaning of the word "indirectly" and is not considering other aspects of the meaning of this word. The term "indirectly" does not necessarily mean that human intervention is required for using the sequence that hybridizes to SEQ ID NO:4 or 11 to indirectly identify another sequence as suggested by Examiner. Rather, the word "indirect" in the context of protein production includes a sequence which hybridizes to SEQ ID NO:4 or 11 and serves as a template for production of SEQ ID NO:4 or 11 which in turn codes for a polypeptide. Thus, "indirectly" also includes a process of producing protein comprising transcription and translation, as compared to translation alone. For example, in the double-stranded cDNA molecule(s) described at paragraph [0148] bridging pages 52-53, the sequence that hybridizes to SEQ ID NO:4 or 11 serves to code for the mRNA, and thereby indirectly results in polypeptide production; while the mRNA that corresponds to SEQ ID NO:4 or 11 (except U's replace T's) directly encodes the polypeptide.

Rejection under 35 U.S.C. 112, second paragraph

In Item 6 at page 13 of the Action, claims 9 and 48 are rejected under 35 USC 112, second paragraph for allegedly lacking antecedent basis in claim 73 with respect to the feature "a conservative variant thereof". These claims have been amended so that this phrase is now cancelled. Withdrawal of this rejection is respectfully requested.

Claim Objections

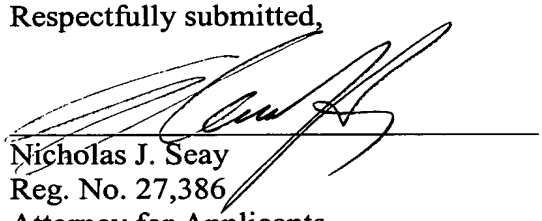
In Item 7 of the Action, Examiner objects to claims 10 and 74 for depending from a rejected base claim Claims 10 and 74 each depend from claims 73 and 8. As indicated in Item 3 of the Advisory Action, the rejection of claims 73 and 8 is overcome by the present amendment. Therefore, withdrawal of this objection is requested.

Applicant respectfully submits that in view of the above amendments and comments all pending claims would appear to be in an allowable form.

It is respectfully submitted that the above-identified application is now in a condition for allowance and favourable reconsideration and prompt allowance of these claims are

respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,



Nicholas J. Seay
Reg. No. 27,386
Attorney for Applicants
QUARLES & BRADY LLP
P.O. Box 2113
Madison, WI 53701-2113

TEL (608) 251-5000
FAX (608) 251-9166